

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**In re: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

All Cases

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**RESPONSE TO CVS AND WALGREENS' OBJECTION TO SPECIAL MASTER'S
ORDER REGARDING FLORIDA DISPENSING DATA**

I. INTRODUCTION

Discovery Ruling 22 (“DR 22”) requires all Defendants, including CVS and Walgreens, to re-produce data and documents produced in related state court actions into the MDL. The Court has repeatedly emphasized the importance of this repository order, noting last summer that it “undoubtedly promotes efficiency by requiring Defendants to reproduce in the MDL documents and information they already have produced elsewhere.” (Dkt. 3333 at 3.) But the Order only works when Defendants comply.

A Florida court ordered CVS and Walgreens to produce anonymized dispensing data in that state litigation. But CVS and Walgreens refused to produce that data into the MDL as required by DR 22. Following briefing, the Special Master ordered Defendants to follow DR 22 and reproduce the data. Dkt. 3667 (“Florida Data Order”). This Objection (“Obj.”), Dkt. 3698, followed. The Special Master did not err by requiring CVS and Walgreens to comply with DR 22.

Defendants object to the Florida Data Order on three baseless grounds. *See* Obj. at 4-5. First, they allege that Plaintiffs failed to follow a process for ensuring proportionality for new discovery requests, which does not pertain to DR 22 productions. Second, they quote inapplicable language from DR 22 related to HIPAA-protected information “provided to a government entity,”

omitting the clarification and context that shows it applies only to government *investigations*, not civil litigation. Third, they argue that the Florida Data Order independently violates HIPAA, without referencing the HIPAA exception that allows it. Special Master Cohen rejected each of these arguments, and, respectfully, the Court should do the same.

II. BACKGROUND

In CMO 1, dated April 11, 2018, the Court ordered Defendants to produce to the MDL Repository non-privileged, relevant documents that were “previously produced pursuant to any civil investigation, litigation, and/or administrative action by federal (including Congressional,) state, or local government entities involving the marketing or distribution of opioids. . . .” Dkt. 232 at 15, ¶ 9.kii.

Special Master Cohen issued Discovery Ruling 22 on September 6, 2019. That ruling provides:

Defendants shall produce in discovery in this MDL copies of all sworn statements, testimony, video-taped testimony, written responses and discovery, expert reports, and other documents and discovery that they produce in any court case, government investigation, or government hearing, regarding the marketing, sales, distribution, or dispensing of Opioids or Opioid products, including any exhibits referred to in that testimony, on an ongoing basis, for the Track Two¹ cases; except Defendants shall not produce any privileged materials, and instead shall produce privilege logs listing those materials, as has been the existing practice.

DR 22, Dkt. 2576 at 4.

Certain Defendants, including CVS and Walgreens, filed limited objections to the discovery ruling at that time. Defendants sought to exclude from the scope of DR 22 materials produced in pending government investigations. Pharmacy Defendants’ Sept. 24, 2019 Letter to Special Master (Exhibit A) at 1. But notably, the Pharmacy Defendants stated that they “do not

¹ On February 21, 2020, the Court issued an Order explaining that DR 22 applied to Defendants in all MDL cases, notwithstanding language that appears to limit it to Track Two cases. Dkt. 3178.

object to producing documents relating to retail opioid sales or dispensing (collectively “dispensing”) that are produced in opioid cases similar to Track 2 (*i.e.* opioid cases filed by states or municipalities seeking damages/and or abatement.” *Id.* at *4. They objected only on the grounds that dispensing data provided to government entities might be fully identified pursuant to a HIPAA exemption for disclosures for law enforcement purposes (45 C.F.R. § 164.512(f)) that does not apply in civil litigation. *Id.* Defendants expressly stated that they *did not* object to the re-production of dispensing data produced in related cases brought by states.

In response, on October 3, 2019, Special Master Cohen amended DR 22 to clarify that it did not require the production of grand jury information, information from pending federal investigations, or “discovery provided to a *government entity* that contains HIPAA-protected information.” Dkt. 2712 at 2 (emphasis added). That Order further clarified that nothing in DR 22 precludes Plaintiffs from requesting a document produced or disclosed in a civil action with a government entity plaintiff. *Id.* at 3. Defendants did not object to the October 3, 2019 Amendment to DR 22.

On May 8, 2020, Special Master Cohen issued an order requiring that the PEC be informed whenever a Defendant receives notice that a pending federal investigation has concluded. Dkt. 3291. On May 21, 2020, Defendants objected to this, as well as the entirety of the re-production obligation set forth in CMO 1 and DR 22, in light of the Sixth Circuit’s mandamus ruling. Dkt. 3299.

On June 15, 2020, the Court denied Defendants’ attempt to have DR 22 vacated in light of the Sixth Circuit’s mandamus ruling, as Defendants had “long ago” waived any such objection. Dkt. 3333 at 2.

Nonetheless, Defendants have refused to produce dispensing data from a Florida state court proceeding, *State of Florida v. Purdue Pharma L.P. et al.*, No. 2019-CA-001438 (Fl. Cir. Ct., Pasco Cty.) (Nov. 20, 2020–Walgreens Order) (copy attached). Special Master Cohen, when presented with the dispute, ordered the Defendants to comply with DR 22. Dkt. 3667. Special Master Cohen addressed Defendants’ objections squarely and correctly, and the Court should affirm his ruling.

III. ARGUMENT

A. The Re-Production Obligation Stems from DR 22 and Is Expressly Authorized by CMO 1, Not the Court’s June 17, 2020 Order.

Defendants first argue that the mechanism outlined in this Court’s June 17, 2020 Order applies to this dispute because it governs any request for dispensing data outside of Ohio, which Defendants argue is newly propounded discovery that must be subject to a relevancy and proportionality analysis. But the production of the Florida Data is expressly authorized and compelled by CMO 1 and DR 22, and not pursuant to any newly propounded discovery request governed by the June 17, 2020 Order.

This Court’s June 17, 2020 Order addressed Plaintiffs’ Motion for Leave to Take Discovery of Pharmacy Defendants’ Nationwide Dispensing Data. Dkt. 3341. In that motion, Plaintiffs sought leave to propound requests for new discovery, as CMO 1 provides that “[n]o party may conduct any discovery of another party in this MDL proceeding not expressly authorized by this Order absent further Order of this Court or express agreement of the parties.” Dkt. 232 at 12 (¶ 9.a) (Apr. 1, 2018). The Court found the request premature, given the pending motions to dismiss the dispensing claims, but stated that if the claims survived the motions to dismiss the PEC would be allowed to propound those requests and that the Pharmacy Defendants would then be able to object to the requests on proportionality grounds. *Id.*

Defendants argue that Plaintiffs were required to follow that guidance in order to request the Florida Data. The background of the Court’s June 17, 2020 Order shows how illogical Defendants’ argument is. The underlying motion was for leave to propound discovery requests that went beyond the scope of discovery expressly authorized by CMO 1 by requiring Defendants to locate, collect, and produce nationwide dispensing data not previously produced in any action. In contrast, CMO 1 expressly allows Plaintiffs to identify productions from related cases that should be re-produced into the MDL repository, such as the Florida Data. Dkt. 232 at 12 (¶ 9.k.iii) (Apr. 1, 2018). DR 22 further clarifies this obligation. Plaintiffs did not propound a new Rule 34 request for production for the Florida Data because Defendants were already obliged to re-produce the data based on CMO 1 and DR 22.

The Court assessed the impact of the Sixth Circuit’s mandamus ruling on DR 22 on June 15, 2020. Dkt. 3333. The Court found that from the outset Defendants committed to producing in the MDL Repository documents from related cases, and that DR 22’s re-production requirement is consistent with the Sixth Circuit’s mandamus ruling. “[T]he key word is ‘*re-produce*’ – the information that DR 22 requires Defendants to produce in the MDL is discovery that Defendants have already located, collected, filtered for privilege, and produced elsewhere. The burden imposed by DR 22 is virtually zero.” *Id.* at 3, emphasis original.

Special Master Cohen properly concluded that the question was not proportionality or relevance, but merely whether the Florida Data was subject to DR 22. This analysis is correct. Moreover, even if the Court were now to consider a proportionality objection to the application of DR 22 to the Florida Data, the only plausible conclusion would be that it is proportional because the burden of production is “virtually zero.” Moreover, Plaintiffs have alleged that pill migration from high-supply areas, like Florida, to high-demand areas, like Ohio, contributed to the opioid

epidemic in Ohio. *See* Dkt. 3294-1 at ¶547 (“Residents of Ohio and other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals ‘prescription tourists.’”).

Special Master Cohen noted these allegations in his order, but indicated that he had not been presented with arguments regarding the relevance or admissibility of Florida dispensing data in Track Three cases. *See* Florida Data Order at 2, n.1.² Pill migration to Ohio from Florida, among other jurisdictions, has been both publicly reported, *see, e.g., 16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html>, and documented in discovery. The Court is well aware of this information from prior briefing. *See, e.g.,* Pls’. Mem. Of Law in Opp’n to Walgreens Mot. Summ. J., at WAGMDL00387976, MDL No. 2804, ECF No. 2205-9 (April 7, 2011 Memorandum of Understanding between the DEA and Walgreens acknowledging improper filling of out-of-state prescriptions); MDL No. 2804, ECF No. 2300-13; MSJ Opp’n Ex. 63, at MNK-T1_0002694677 (2012 Mallinckrodt presentation showing a geographic analysis of cash transactions for oxycodone, explaining “[o]ne can also follow the ‘oxy express’ (highway 75) and see all the cool spots that pop up along the highway known to be used by drug seekers travelling for pills (according to the [DEA].)”); *and see, e.g.,* Order Denying Walgreen’s Motion for Summary Judgment at 3, MDL No. 2804, ECF No. 2569 (discussing evidence Plaintiffs presented that “Walgreens’ lax approach to monitoring diversion at [a Florida] facility was standard operating procedure nationwide.”). Thus, even if a relevancy analysis were to apply to DR 22 productions, which it does not, Plaintiffs easily satisfy the relevancy threshold for discovery under Fed. R. Civ. P. 26(b)(1).

² As set forth in Fed. R. Civ. P. 26(b)(1), “[i]nformation within this scope of discovery need not be admissible in evidence to be discoverable.”

B. DR 22 Compels Re-Production of the Florida Data, Notwithstanding an Inapplicable Exception for Disclosures for Government Investigations

Defendants next argue that re-production of the Florida dispensing data is precluded by the “plain terms of DR 22,” based on an amendment to the Discovery Ruling that does not apply. The exception that Defendants cite reads: “Pharmacy Defendants are not obligated by DR-22 to produce in the MDL any discovery provided to a government entity that contains HIPAA-protected information.” As described above, the Special Master added this language in his October 3, 2019 Order amending DR 22 to address the Pharmacy Defendants’ concerns regarding production to government entities in the course of an opioid-related investigation. Dkt. 2712 at 2, The Order and the language of Defendants’ request confirm that the “government entity” exception only applies to information provided to government entities during the course of an investigation, not separate litigation.

Defendants selectively quote from the October 3, 2019 Amendment to create the impression that that ruling exempted from DR 22 any HIPAA-protected information provided to a government entity in the course of civil litigation. In fact, the rest of the Amendment makes clear that it does not. On the very next page, the Special Master further amended DR 22 to make clear that “[n]othing in this Order shall preclude Plaintiffs from requesting from Defendants any document that they produce or disclose in any criminal or civil action filed by a governmental entity, even if the same document was previously provided by the Defendant to the government entity during the course of a government investigation.” Dkt. 2712 at 3.

This makes sense when viewed in context with Defendants’ argument for the Amendment. Defendants sought the Amendment by referencing the HIPAA exception allowing covered entities to disclose protected health information for law enforcement purposes. Pharmacy Defendants’ Sept. 24, 2019 Letter to Special Master (Exhibit A) at 4 (citing 45 C.F.R. § 164.512(f), the “law

enforcement” exception). In that motion, Defendants expressly stated that they would be willing to re-produce documents relating to opioid dispensing that are produced in “opioid cases filed by states or municipalities.” *Id.*

The Florida dispensing data is not within the “law enforcement” exception to HIPAA which formed the inspiration for the Amendment. It is discovery produced in civil litigation brought by an attorney general, exactly the material Defendants represented they would be willing to produce, and which the Amendment clarifies remains subject to DR 22.³

C. The Florida Data Is Sufficiently Anonymized and Re-Production of the Florida Data Squarely Fits Within a HIPAA Exception

Defendants’ final argument is that re-producing the Florida data would violate HIPAA. It would not. First, the information is sufficiently anonymized. Second, even if the data does not satisfy the de-identification standards of 45 C.F.R. 164.514, its production is pursuant to a court order where there is a protective order in place, making the release appropriate under the HIPAA exception for judicial and administrative proceedings.

As Special Master Cohen found, the Florida Data is sufficiently anonymized. Dkt. 3667 at 3. Personal health information is de-identified under § 164.514 when there is “no reasonable basis to believe that the information can be used to identify an individual,” based on either the documented results of an expert’s methodology, (164.514(b)(1)), or if 18 categories of enumerated personally identifiable information have been removed, (164.514(b)(2)).

Of the 71 data fields in the Florida Data, only four are arguably included in the regulation’s enumerated list. When considering production of Ohio dispensing data including these precise four

³ As discussed *supra*, the Florida dispensing data is subject to a wholly separate HIPAA exception, 164.512(e), the “judicial and administrative proceedings” exception. *See e.g. Jacobs v. Connecticut Cmty. Tech. Colleges*, 258 F.R.D. 192, 197 (D. Conn. 2009) (finding subsection (e) the applicable exception when defendant state attorney general sought plaintiff’s personal health information in the course of litigation.)

data fields, Special Master Cohen previously found that the data was sufficiently de-identified, such that “[t]he end result is that no person who obtains the data will learn what medications any identifiable individual has received.” Dkt. 3106 at 8 (“Pharmacy Data Production Order”). Defendants objected to this ruling, Dkt. 3149, and the Court overruled their objections, Dkt. 3170. In that Order, the Court found that the Special Master’s Pharmacy Data Production Order reflected a “reasoned exercise of discretion,” and that when “viewed in light of the set of data fields to be produced,” the challenged data fields did not risk patient privacy. *Id.* The same analysis applies here, as the Special Master correctly found.

What’s more, the re-production squarely fits within a HIPAA exception. The HHS regulation entitled “Disclosures for Judicial and Administrative Proceedings,” §164.512(e), authorizes a “covered entity” (such as Defendants) to disclose private health information in judicial or administrative proceedings “in response to an order of a court.” §164.512(e)(1)(i). The regulation also allows the disclosure of such information in proceedings “in response to a subpoena, discovery request, or other lawful process,” §164.512(e)(1)(ii), if the party seeking the information makes a “reasonable effort” to secure a qualified protective order, that is, an order that prohibits the use or disclosure of the information outside the litigation and requires the return or destruction of the information at the end of the litigation. 45 C.F.R. § 164.512(e)(1)(v).

More than “reasonable efforts” to secure a protective order have been made—an order authorizing production of Personal Health Information has been in place for years. *See* CMO-2, Dkt. 441, at ¶¶ 70-77. CMO-2 specifically provides: “Pursuant to 45 C.F.R. § 164.512(e)(1), all Covered Entities . . . are hereby authorized to disclose Protected Health Information pertaining to the Action to those persons and for such purposes as designated herein.” *Id.* at ¶ 74. As the re-

production of the Florida Data is in response to an order of a Court, DR 22, and there is a qualified protective order in place, it is clearly exempted from HIPAA's disclosure restriction.

IV. CONCLUSION

For the foregoing reasons, the Court should overrule the Defendants' Objection (Dkt. 3698) to the Special Master's March 30, 2021 discovery order (Dkt. 3667).

DATED this 22nd day of April, 2021.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this April 22, 2021, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/Peter H. Weinberger
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